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EXAMINER
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ART UNIT	PAPER NUMBER
1648	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/713,687	WATOWICH ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6,49-51,53,55-60 and 66-74* is/are pending in the application.

4a) Of the above claim(s) *56-59 and 68-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 6, 49-51, 53, 55, 60 and 66-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 5-6, 49-51, 53, 55-60, and 66-74 are pending.

Response to Amendment

This is a response to the amendment, paper No. 12, filed 02/10/03. Claims 7, 52, 54, and 61-65 are canceled. Claims 5-6, 49, 51, 53, 55 and 60 have been amended. New claims 66-74 have been added.

Election/Restrictions

The newly added claims 68-74 are directed to another eukayotic virus pseudocapsid and a method of making the same, which are structural distinct from the one in the elected group. Therefore, they are restricted from the elected group and not considered before the examiner.

Claims 5-6, 49-51, 53, 55, 60 and 66-67 are considered.

Applicants are reminded to cancel the claims 56-59 and 68-74 drawn to the non-elected group.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New matter

The amendment filed paper no. 12, 02/10/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: (1). claim 5, lines 6-7: after which no additional purification step is required"; (2). claim 6, line 2: " homologous sequence of a core protein from a member of the flavivirus family"; (3). claim 49, line 2; " of at least 10 nucleotides"; (4). claim 55, line 3: " and member of the flavivirus family"; (5). claim 60, lines 3, and lines 5-6: "a cell free system" and " a homologous sequence of a core protein from a member of the flavivirus family"; and (6). claims 68-74 also introduce a new matter because the claimed invention drawn to a pseudo-nucleocapsid and a method for making the pseudonucleocapsid with a sequence comprising a hepatitic C core protein and a homologous sequence of a core protein from a member of the flavivirus family mixed with a polynucleotide

RNA of at least 10 nucleotides that form stem-loop structure were not supported by the disclosure as the Application was originally filed. Applicant is required to cancel the new matters in the reply to this Office Action.

New matter Rejection

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the added materials that are not supported by the original disclosure is as follows: (1). claim 5, lines 6-7: after which no additional purification step is required"; (2). claim 6, line 2: " homologous sequence of a core protein from a member of the flavivirus family"; (3). claim 49, line 2; " of at least 10 nucleotides"; (4). claim 55, line 3: " and member of the flavivirus family"; (5). claim 60, lines 3, "a cell free system" and line 5-6: a homologous sequence of a core protein from a member of the flavivirus family"; and (6) claims 68-74 also introduce a new matters because the claimed invention drawn to a pseudo-nucleocapsid and a method for making the pseudonucleocapsid with a sequence comprising a hepatitic C core protein and a homologous sequence of a core protein from a member of the flavivirus family mixed with a polynucleotide RNA of at least 10 nucleotides that form stem-loop structure were not supported by the disclosure as the Application was originally filed. Applicant is required to cancel the new matters in the reply to this Office Action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 5-7, 49-55 and 60-65 are still rejected under 35 U.S.C. 112, second paragraph on the same ground as stated in the previous Office Action, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 5-6, 53, 55, and 60 are still rejection for recitation of "consisting essentially" Applicants argue that since the " First, the phrase "comprising at least " has been changed to "consisting essential of", the rejection should be withdrawn.

4. Applicants' argument has been respectfully considered; however, it is not found persuasive because in the instant case, in combination of the cited language of " at least" and "comprising at least" in the amended claim, the examiner would broadly interpret the claim encoding a sequence more than the first 124 amino acid residues of any or all HCV core gene , rather than SEQ ID NO. 1 . Accordingly the examiner should apply art in the event that such art is available. The examiner now states on the record that the other elements of the prior art (if there are other elements present) do not appear to materially change the characteristics of the protein. In this way applicant will come forth with evidence to show that the extraneous elements in the reference do indeed have a material effect on the characteristics of the protein. According to the MPEP " [it] is an applicant's burden to establish that other element in a prior art method is excluded from his claims by "consisting essentially of" language." Please see MPEP 2111.03.

5. Furthermore, claims are also vague in that the metes and bounds of "homologous sequence of a core protein from a member of the Flavivirus family" are not defined. The claim is interpreted in light of the specification; however, the specification does not teach which "homologous sequence " is. Applicants are reminded that identity, homology or sequence similarity can be calculated by a variety of different methods, whereby the calculated identity between two sequences will be quite different depending on the algorithm used for calculation. The specification has no indication of the utilized algorithm to calculate the homology of a sequence. Furthermore, the calculation of "homology" is affected by variables such as the relative weight given to the sequence gaps versus mismatches, or whether conservative substitutions are weighted differently from non-conservative substitutions. In addition, claims are indefinite in that it fails to define the boundary of ' a member of the flavivirus family" .

6. Claim 6 is also rejected by lack of insufficient antecedent basis because the recitation of the limitation "the" in Flavivirus is not cited in the claim previously.

7. Furthermore, claim 5 is still rejected on the same ground as the metes and bounds of "a polynucleotide" are not defined for the same reason as stated in the previous Office Action. Applicants have not address this issue in response to the previous Office Action.

8. The above rejections are still affects the dependent claims 49-51, 55, 60, and 66-67.

Claim Rejections - 35 USC § 112

9. Claims 5-7, 49-56 and 61-65 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as sated in the previous Office Action, because the specification, while being enabling for having a HCV pseudo-nucleocapsid made by incubating the mixture of HCV core protein encoded by SEQ ID NO: 1 and tRNA in an in vitro array system, does not reasonably provide enablement for having any or eukaryotic virus pseudo-nucleocapsid comprising any or all a portion of viral capsid polypeptide and a polynucleotide formed in any or all in vitro system. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

10. Applicants traverse the rejection and submit that the amendments of claims 5-6, 49, 51, 53, 55 and 60, which limit the polypeptide comprising at least the first 124 amino-terminal residues of hepatitis C virus core protein or a homologous sequence of a core protein from a member of the Flavivirus family and polynucleotide if from the group consisting essential of hepatitis C virus genome and member of the Flavivirus family, preferably with at least 10 nucleotides, would be able for one of skill in the relevant art to make and use the claimed invention without undue experimentation.

Applicants' argument as well as the amendment have been respectfully considered; however, it is not found persuasive because considering the broad scope of the claimed invention still read on an eukaryotic virus pseudo-nucleocapsid made by any or all portion of a virus polypeptide homologous sequence to the hepatitis C virus core antigen plus any or all polynucleotide of family of Flavivirus, at least comprising 10 nucleotides that are assembled in any or all in vitro setting system, specification still lacks of adequate teaching precisely which polypeptide homologous sequence of a member of Flavivirus and which 10 nucleotides in a polynucleotide are intended. In addition, Applicant's arguments with respect to claims 5, 6, 49,

55, 60 have been considered but are moot in view of the new ground(s) of rejection set forth in the new matter rejection and 112 written description rejection. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 5-7, 49, 51, 52, 53, 54, 55 and 60-65 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Baumert et al. (J. Virol. 1998, Vol. 72, pp. 3827-3836).

13. Applicants traverse the rejection and submit that according to the amendment of claim 5, which is amended to limited the polypeptide used to form viral like particle comprising at least first 124 amino terminal residue of a hepatitis C virus core protein and after which no additional purification step is required. Applicants further asserted that Baumer et al. does not disclose, either implicitly or explicitly, an eukaryotic virus pseudo-nucleocapsid formation with at least " 124 amino-terminal residues of a hepatitis C virus.

14. Applicants' argument has been respectfully considered; however, it is not found persuasive because in combination of the cited language of " at least" and "comprising at least" in the amended claim 5, the examiner would broadly interpret the claim encoding a sequence more than the first 124 amino acid residues of any or all HCV core gene , rather than SEQ ID NO. 1 . Accordingly the examiner should apply art in the event that such art is available. The examiner now states on the record that the other elements of the prior art (if there are other elements present) do not appear to materially change the characteristics of the protein. In this way applicant will come forth with evidence to show that the extraneous elements in the reference do indeed have a material effect on the characteristics of the protein or amend the claimed polypeptide to a precise SEQ ID NO. According to the MPEP " [it] is an applicant's

burden to establish that other element in a prior art method is excluded from his claims by "consisting essentially of" language." Please see MPEP 2111.03.

15. Regarding to the limitation of in vitro system and no additional purification is required, Applicants are reminded that claims 5-7, 49, 51, 52, 53, 54, 55 and 60-65 are product-by-process type claims. The MPEP discusses product-by -process claims in chapter 2100: Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, the rejection is maintained.

16. Claims 5, 6, 7, 49-52, 54-55 and 61-65 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Yasui et al. (J. Virol. 1998, Vol. 72, pp. 6048-6055).

17. Applicants traverse the rejection and submit that according to the amendment of claim 5, which limits the polypeptide used to form viral like particle comprising at least first 124 amino terminal residue of a hepatitis C virus core protein and after which no additional purification step is required. Applicants further asserted that Yasui et al. does not disclose, either implicitly or explicitly, an eukaryotic virus pseudo-nucleocapsid formation with at least " 124 amino-terminal residues of a hepatitis C virus.

18. Applicants' argument has been respectfully considered; however, it is not found persuasive because in combination of the cited language of " at least" and "comprising at least" in the amended claim 5, the examiner would broadly interpret the claim encoding a sequence more than the first 124 amino acid residues of any or all HCV core gene , rather than SEQ ID NO. 1 . Accordingly the examiner should apply art in the event that such art is available. The examiner now states on the record that the other elements of the prior art (if there are other elements present) do not appear to materially change the characteristics of the protein. In this way applicant will come forth with evidence to show that the extraneous elements in the reference do indeed have a material effect on the characteristics of the protein or amend the claimed polypeptide to a precise SEQ ID NO. According to the MPEP " [it] is an applicant's

burden to establish that other element in a prior art method is excluded from his claims by "consisting essentially of" language." Please see MPEP 2111.03.

19. Regarding to the limitation of in vitro system and no additional purification required, Applicants are reminded that claims 5-7, 49, 51, 52, 53, 54, 55 and 60-65 are product-by-process type claims. The MPEP discusses product-by -process claims in chapter 2100: Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, the rejection is maintained.

20. Claims 5, 6, 7, 49-52, 54-55 and 61-65 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Liang et al. (WO 98/21338A1).

21. Applicants traverse the rejection and submit that according to the amendment of claim 5, which limits the polypeptide used to form viral like particle comprising at least first 124 amino terminal residue of a hepatitis C virus core protein and after which no additional purification step is required. Applicants further asserted that Liang et al. does not disclose, either implicitly or explicitly, an eukaryotic virus pseudo-nucleocapsid formation with at least " 124 amino-terminal residues of a hepatitis C virus.

22. Applicants' argument has been respectfully considered; however, it is not found persuasive because in combination of the cited language of " at least" and "comprising at least" in the amended claim 5, the examiner would broadly interpret the claim encoding a sequence more than the first 124 amino acid residues of any or all HCV core gene , rather than SEQ ID NO. 1 . Accordingly the examiner should apply art in the event that such art is available. The examiner now states on the record that the other elements of the prior art (if there are other elements present) do not appear to materially change the characteristics of the protein. In this way applicant will come forth with evidence to show that the extraneous elements in the reference do indeed have a material effect on the characteristics of the protein or amend the claimed polypeptide to a precise SEQ ID NO. According to the MPEP " [it] is an applicant's

burden to establish that other element in a prior art method is excluded from his claims by "consisting essentially of" language." Please see MPEP 2111.03.

23. Regarding to the limitation of in vitro system and no additional purification required, Applicants are reminded that claims 5-7, 49, 51, 52, 53, 54, 55 and 60-65 are product-by-process type claims. The MPEP discusses product-by -process claims in chapter 2100: Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, the rejection is maintained.

24. Claims 5, 6, 49-51, and 61-63 are still rejected under 35 U.S.C. 102(b) on the same ground as stated in the previous Office Action as being anticipated by Wengler et al. (Virol. 1982, Vol. 118, pp. 401-411).

25. Applicants traverse the rejection and submit that according to the amendment of claim 5, which limits the polypeptide used to form viral like particle comprising at least first 124 amino terminal residue of a hepatitis C virus core protein and after which no additional purification step is required. Applicants further asserted that Wengler et al. does not disclose, either implicitly or explicitly, a eukaryotic virus pseudo-nucleocapsid formation with at least " 124 amino-terminal residues of a hepatitis C virus.

26. Applicants' argument has been respectfully considered; however, it is not found persuasive because in combination of the cited language of " at least" and "comprising at least" in the amended claim 5, the examiner would broadly interpret the claim encoding a sequence more than the first 124 amino acid residues of any or all HCV core gene , rather than SEQ ID NO. 1 . Accordingly the examiner should apply art in the event that such art is available. The examiner now states on the record that the other elements of the prior art (if there are other elements present) do not appear to materially change the characteristics of the protein. In this way applicant will come forth with evidence to show that the extraneous elements in the reference do indeed have a material effect on the characteristics of the protein or amend the claimed polypeptide to a precise SEQ ID NO. According to the MPEP " [it] is an applicant's

burden to establish that other element in a prior art method is excluded from his claims by "consisting essentially of" language." Please see MPEP 2111.03.

27. Regarding to the limitation of in vitro system and no additional purification required, Applicants are reminded that claims 5, 6, 49-51, and 61-63 are product-by-process type claims. The MPEP discusses product-by -process claims in chapter 2100: Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

28. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

29. Claims 5, 6, 7, 49-52, 54, 55 and 61-65 are still rejected under 35 U.S.C. 102(a) on the same ground as stated in the previous Office Action as being anticipated by Falco et al. (Tissue & Cell, 1999, Vol. 31, pp. 117-125).

30. Applicants traverse the rejection and submit that according to the amendment of claim 5, which limits the polypeptide used to form viral like particle comprising at least first 124 amino terminal residue of a hepatitis C virus core protein and after which no additional purification step is required. Applicants further asserted that Falco et al. does not disclose, either implicitly or explicitly, a eukaryotic virus pseudo-nucleocapsid formation with at least " 124 amino-terminal residues of a hepatitis C virus.

31. Applicants' argument has been respectfully considered; however, it is not found persuasive because in combination of the cited language of " at least" and "comprising at least" in the amended claim 5, the examiner would broadly interpret the claim encoding a sequence

more than the first 124 amino acid residues of any or all HCV core gene , rather than SEQ ID NO. 1 . Accordingly the examiner should apply art in the event that such art is available. The examiner now states on the record that the other elements of the prior art (if there are other elements present) do not appear to materially change the characteristics of the protein. In this way applicant will come forth with evidence to show that the extraneous elements in the reference do indeed have a material effect on the characteristics of the protein or amend the claimed polypeptide to a precise SEQ ID NO. According to the MPEP " [it] is an applicant's burden to establish that other element in a prior art method is excluded from his claims by "consisting essentially of" language." Please see MPEP 2111.03.

32. Regarding to the limitation of in vitro system and no additional purification required, Applicants are reminded that claims 5, 6, 49-51, and 61-63 are product-by-process type claims. The MPEP discusses product-by -process claims in chapter 2100: Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, the rejection is maintained.

New Ground of Rejections:

Claim Rejections - 35 USC § 112

33. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

34. Claims 66 and 67 are indefinite in that the recitation of " consisting essential of at least " are open language which fail to define the structural characteristic of the claimed polypeptide for the same notion as described supra in the rejection of claims 5 and 53.

35. Claims 49 and 66-67 are indefinite in that the metes and bounds of " at least 10 nucleotides" are not defined. The claim is interpreted in light of the specification; however, the

specification does not teach which 10 nucleotide sequence" are intended? Are they a sequence containing a contiguous 10 nucleic acids or non-contiguous 10 nucleic acids?

36. Claims, 6, 55 and 60 are indefinite in that the metes and bounds of " member of Flavivirus family" are not defined.

Claim Rejections - 35 USC § 112

37. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

38. Claims 6, 49, 51, 53, 55 and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

39. In the instant case, the applicants have only disclosed that a HCV pseudo-nucleocapsid is able to be made by incubating the mixture of HCV core protein encoded by SEQ ID NO: 1 and tRNA in an in vitro array system. The specification does not have enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed at least any homologous sequence to the hepatitis C core protein with at least 10 nucleotides of a polynucleotide may encompass. Therefore, a written description of the other claimed sequences, which are homology of SEQ ID NO: 1 or core antigen of hepatitis C and any sequence of 10 nucleotides of a polynucleotide tRNA, should be disclosed to overcome this rejection. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that "a patent specification contain a written description of the invention and the manner and

process of making and using it in such full clear and concise terms as to enable one skilled in the art to make and use the invention". Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

Claim Rejections - 35 USC § 102

40. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

41. Claim 60 is rejected under 35 U.S.C. 102(b) as being anticipated by Sugrue et al. (J. General Virol. 1997, Vol. 78, pp. 1861-1866).

42. In response to the Office Action, Applicants amended claim to a virus psuedo-nucleocapsid, wherein the said viral capsid polypeptide is formed by a homologous sequence of a core protein from a member of the flavivirus, the claimed invention is anticipated by the cited reference of Sugrue et al. because Sugrue et al. disclose a method of making a viral like particle of dengue virus by using the cDNA encoding the Dengue virus structural protein C and two membrane proteins, E and M. The Dengue virus is a member of flavivirus and C protein is the homologous sequence of HCV core protein and the viral like particle is formed in a yeast cell system.

43. Regarding to the limitation of in vitro system and no additional purification is required, Applicants are reminded that claims 5-7, 49, 51, 52, 53, 54, 55 and 60-65 are product-by-process type claims. The MPEP discusses product-by -process claims in chapter 2100: Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its

method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, the rejection is maintained.

44. Claim 60 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamshchikov et al. (Virol. 1993, Vol. 192, pp. 38-51).

45. In response to the Office Action, Applicants amended claim to a virus psuedo-nucleocapsid, wherein the said viral capsid polypeptide is formed by a homologous sequence of a core protein from a member of the flavivirus, the claimed invention is anticipated by the cited reference of Yamshchikov et al. because Yamshchikov et al. teach a pseudo type of viral like particle made by Denue virus capsid protein C plus other proteins, such as pre-M-E as well as NS2B etc. The pseudo virus like particles are assembled in human TK1143B cell line and Hela T4 cells, which is a mammalian host cell system. The Denue virus is a flavivirus and the pseudo-virus like particle comprises capsid C protein and other recombinant protein as well as polynucleotide (See entire document).

46. Regarding to the limitation of in vitro system and no additional purification is required, Applicants are reminded that claims 5-7, 49, 51, 52, 53, 54, 55 and 60-65 are product-by-process type claims. The MPEP discusses product-by -process claims in chapter 2100: Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, the rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
May 1, 2003

James C. Housel 5/4/03
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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